

**NATIONAL CANCER INSTITUTE AT FREDERICK (NCI@F)**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**  
**MINUTES**  
**APRIL 21, 2015**

**CALL TO ORDER / ANNOUNCEMENTS**

The NCI at Frederick Institutional Biosafety Committee was convened at 12:05 pm in Building 549 Executive Board Room with the following members in attendance:

Voting (Quorum = 8)

- |  |  |
|--|--|
| <input checked="" type="checkbox"/> Michael Baseler              | <input type="checkbox"/> Sarah Hooper ( <i>regrets</i> ) |
| <input checked="" type="checkbox"/> Theresa Bell                 | <input checked="" type="checkbox"/> Serguei Kozlov       |
| <input checked="" type="checkbox"/> Rev. David Betzner           | <input checked="" type="checkbox"/> Dan McVicar          |
| <input checked="" type="checkbox"/> Stephen Creekmore            | <input checked="" type="checkbox"/> Raja Sriperumbudur   |
| <input checked="" type="checkbox"/> Bruce Crise                  | <input checked="" type="checkbox"/> Lucien Winegar       |
| <input checked="" type="checkbox"/> Eric Freed                   | <input checked="" type="checkbox"/> Sharon Altmann       |
| <input type="checkbox"/> Melinda Hollingshead ( <i>regrets</i> ) | <input checked="" type="checkbox"/> Patti Labbe          |
| <input checked="" type="checkbox"/> Stephen Hughes               |  |

Non-Voting

- Walter Hubert
- Karen Barber

**APPROVAL OF MINUTES FROM THE MARCH 17TH MEETING**

The minutes from the March 17, 2015 meeting were approved. An addition of Patti Labbe to the roster. A motion and second was made. (For: 12; Against: 0; Abstain: 1 )

**ACCIDENT REVIEWS :**

- Bethesda – NHP accident. Needle stick in the back left leg. Employee had hooked up an IV to the primate and the connection to the catheter dislodged and swung down and hit the employee's leg. No risk to the employee from this line.

**REVIEW OF PROTOCOLS**

***NEW REGISTRATIONS***

- ❖ Jayanta Sinha – 15-17: Storage of CHOP (Children's Hospital of Philadelphia) rAAV-VRC07 recombinant adeno-associated vector - The purpose of this project is solely to store materials that were generated by CHOP (Children's Hospital of Philadelphia) for the production of rAAV-VRC07, a recombinant adeno-associated virus vector engineered for the expression of VRC07 anti-HIV antibody in transformed cells. CHOP has requested VCMP store materials prepared under subcontract with Leidos Biomed. The VRC/NIAID/NIH has approved this request. All materials are frozen and liquid. The materials are stored at low temperature (<-60oC) and are contained in sealed primary and secondary containers. The listing of the materials is attached. The storage

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requirement is 15 cu. ft. The VCMP will not be using this material or opening any of the packaging but will store the material undisturbed. The packages will be visually inspected upon arrival to assure no tears or breaks in the packaging. A motion to approve was made by Dan McVicar and seconded by Steve Creekmore. (For: 13; Against: 0; Abstain: 0)

- ❖ Peter Choyke – 15-19: Preclinical Tests of Novel Molecular Imaging Agents - The goal of these studies is to develop new molecular imaging probes of potential clinical utility for diagnoses of human diseases, particularly cancers. Agents may be radiopharmaceuticals for Positron Emission Tomography (PET) or Single Photon Emission Computed Tomography (SPECT) and/or fluorophore conjugates of targeting agents for optical/fluorescent imaging. Useful imaging probes will be those that detect disease in established animal models, usually in a predictive and specific manner. In addition, useful probes could track disease pathophysiology and be useful in certain instances in monitoring therapeutic responses of various disease states to experimental and novel drug treatment regimens. A motion to approve with clarifications was made by Serguei Kozlov and seconded by David Betzner. (For: 13; Against: 0; Abstain: 0)

***RENEWAL REGISTRATIONS***

- ❖ Cheryl Winkler – 15-06 (10-17): Genetics of Complex Diseases. We use RNA, DNA, and human samples to identify genes and variation associated with human diseases. ***A motion was made to defer to the May meeting with further clarifications.*** (For: 13; Against: 0; Abstain: 0)
- ❖ Dianne Newton – 15-16 (11-29): Preparation of mixed tumor cultures and fibroblasts from patient derived material. To isolate/purify and characterize mixed tumor cell cultures and fibroblasts derived from human patient biopsies/resections received from NIH Clinical Center and IRB approved Comprehensive Cancer Centers across the USA. ***A motion was made to defer to the May meeting with further clarifications.*** (For: 13; Against: 0; Abstain: 0)
- ❖ Drs. Pavlakis and Felber – 15-12 (10-58): Gene Transfer and Expression of Cellular and Viral DNA's – This registration focuses on (A) the identification of mechanisms controlling gene expression and (B) the role of molecular adjuvants in optimization of DNA vaccines and of immunotherapeutic agents for cancer therapy. (McVicar/Crise) ***In progress. Deferred to May meeting per the PI.***
- ❖ Drs. Pavlakis and Felber - 15-13 (07-01): Use of lentiviral/retroviral vectors for gene transfer into mammalian cells. The objective is to use lentiviral/retroviral vectors as a vehicle for gene transfer into mammalian cell lines. We use this system to insert a gene of interest into the packaging vector, generate pseudotyped virions and generate stable modified cell lines. The advantage of using these systems is that only a few copies of a gene of interest are integrated. Lentiviral/retroviral vector systems consists of 3 independent plasmids expressing (a) the gene of interest such as cytokines, cytokine receptors, HIV/SIV genes; (b) the packaging signal and the marker gene like luciferase or Green Fluorescent protein GFP and/or a selection marker like neomycin; (c) the gene for one single round of replication such as env (VSV-G to enter any cells). For this reason, the pseudotyped virions are only competent for a single round of infection. The separation of the packaging signal, LTRs and gag/pol and env genes into separate plasmids

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eliminates the chance of recombination. The plasmids are obtained either from other investigators or are generated by us. A combination of the respective plasmids is transiently transfected into human 293 cells (this work is performed in the BSL-2\* facility) and the supernatant is directly used to infect the cell line of interest such as HEK293 and primary murine cells. We generate stable cell lines (i.e. selecting for neo resistant cells), generating i.e. cell lines expressing the co-receptors CCR5, CXCR4, cytokine, cytokine receptors, or any gene of interest. ***A motion was made to defer to the May meeting with further clarifications.*** (For: 13; Against: 0; Abstain: 0)

**OUTSTANDING ITEMS**

- ❖ Peter Gorelick – 14-26 (08-27): Serological diagnostic testing of non-human primates for the presence of potentially adventitious viruses - Diagnostic serological testing for routine health monitoring of NHPs. (Bell) **Deferred to full committee in August, 2014. Awaiting additional documentation.**
- ❖ Stephen Lockett – 14-22 (08-46): Ras project 3 and CCR support. Discovery methods to directly target oncogenic Ras protein, and live and fixed cell fluorescence labeling in support of CCR research. (Zudaire/Hughes/Altmann) Deferred to full committee in August. Awaiting additional documentation. **ON HOLD. WAITING ON CHANGES IN THE DEPARTMENT BEFORE SUBMITTING. As of October 14, 2014, no updates have been made.**
- ❖ Dimitar Dimitrov 13-38 (04-04, 08-20): Developing anti-viral vaccines and human antibodies against infectious diseases and cancer antigens by using recombinant membrane proteins of HIV, Nipah, Hendra, Dengue viruses and cancer antigens. Committee requested additional clarifications and a Vaccinia-specific SOP as well as a lab visit. Post-meeting, Theresa Bell learned that the lab was relocating and suggested that the space that will be used for the Vaccinia work should not be evaluated until the move has been completed. No Vaccinia work is being performed at this time. **Approved. Need to visit lab space once moved for Vaccinia work.**
- ❖ Ji Ming Wang – 14-46: The role of mouse mFPR2 in the pathogenesis of Helicobacter Pylori. H.pylori infects human stomach to cause inflammation and sometime h.pylori produces peptides that activate a G-protein coupled receptor FPR2 in human and mFPR2 (in mouse, also termed Fpr2) to induce migration of neutrophils and monocytes, therefore may establish a basis for inflammation. The purpose of this proposal is to use mice deficient in Fpr2 to examine their susceptibility to H.Pylori-induced stomach inflammation and potential cancer. A motion to approve with the clarification that a mock observation is to be performed before work begins. **PI has put this observation on hold due to new staffing.** (Creekmore/Hollingshead)

**AMENDMENTS**

Seventeen amendments were processed and approved between February and March IBC meetings.

**OTHER BUSINESS**

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**ADJOURNMENT**

The meeting adjourned at 1:25 pm.

***Next meetings:***

***May 19, 2015***

***June 16, 2015***